

**REMARKS**

Claims 1–10, 12, 15–21, 23 and 26–30 are pending. Reconsideration of the application is requested.

**§ 103 Rejections**

Claims 1, 3, 5–10, 12, 16–18 are rejected under 35 USC § 103(a) as being unpatentable over Lastovich (U.S. Patent Publication 2004/0007796) in view of Clarke (WO 2004/009172).

The Applicants appreciate the Patent Office consideration of the previous arguments presented, but respectfully disagree with the reassertion of the rejection from the previous Office Action.

Lastovich points to a number of different techniques known in the art for making microneedle devices. One method is injection molding using hot runners. Hot runners refers to the practice of heating the reservoir containing the polymer material to be injection molded above the melt temperature of the polymer. The mold is typically not heated.

Alternative methods include embossing. Embossing does not require injection of a molten plastic. Instead, embossing includes pressing into a polymeric substrate a mold that includes an impression of the desired shaped polymer article. Thus, for embossing, the substrate may be heated above its softening temperature or the mold may be heated to above the softening temperature of the substrate, but both are not typically heated, and they are at the very least not heated "in a chamber separate from" one another as claimed.

Another alternative embodiment is compression molding, which includes providing a powder or pelletized material in a mold, closing the mold, and then heating the powder and mold to provide the molded article. Again here, the negative mold cavity and molded plastic material are not heated "in a chamber separate from" one another.

These are three distinct methods for preparing molded plastic articles. The presently claimed invention is yet another new and non-obvious method.

In contrast to anything described in Lastovich, the present claim 1 provides, *inter alia*, "heating the negative mold cavity to a temperature above the softening temperature of a moldable plastic material; heating the moldable plastic material to at least the molten temperature of the moldable plastic material in a chamber separate from the negative mold cavity."

The Patent Office asserts that because in injection molding, hot runners techniques involve heating the plastic material to be injected, and that in embossing the mold may be heated, that it would have been obvious to one of skill in the art to modify the process taught by Lastovich to provide the heating steps described in present claim 1.

Applicants respectfully submit that in fact, the skilled artisan would have understood that the polymer may be heated (e.g., hot runner injection molding), or the mold may be heated (e.g., embossing or compression molding), but one of skill in the art would not have a reason to heat both separately in an injection method as claimed. There is no indication in Lastovich that heating the polymer alone (e.g., hot runner) would be insufficient for creating molded articles. In fact, it is only in the present application, particularly through the examples, that the Applicants have demonstrated and now claim a method capable of providing substantial improvements in filling microstructure mold cavities. See, for instance, Table 1, contrasting Examples 1 and 8 to Comparative Example C1 and Examples 9 and 10 to Comparative Example C2.

Furthermore, while the Patent Office recognizes that Lastovich teaches heating the mold cavity to a temperature above the softening temperature (see paragraph 12, page 4 of the rejection and paragraph [0048] cited by the Patent Office), the claim actually requires heating the thermoplastic material to at least the molten temperature, not the softening temperature.

Thus, one of ordinary skill in the art, in possession of the description in Lastovich, would have understood hot runner injection molding, embossing, or compression molding to constitute three perfectly adequate and distinct methods for making polymeric microneedles. It is only through the present application, however, that one would understand the benefits of the claimed method, as demonstrated by the Applicants' examples. Accordingly, we respectfully reiterate that the Patent Office has failed to establish a *prima facie* case of obviousness of claim 1 over Lastovich.

The Patent Office points to Clarke to overcome the deficiencies of Lastovich in teaching a negative image of a microneedle characterized by an aspect ratio of between 2 to 1 and about 5 to 1. The Patent Office points to nothing in Clarke, however, that helps to overcome the deficiencies of Lastovich in describing other aspects of claim 1, as discussed above. The rejection of claim 1 under 35 USC § 103(a) as being unpatentable over Lastovich in view of Clarke has been overcome and should be withdrawn.

Claims 3, 5–10, 12, 16–18 each add additional features to claim 1. Claim 1 is patentable for the reasons given above. Thus, claims 3, 5–10, 12, 16–18 are likewise patentable.

In summary, the rejection of claims 1, 3, 5–10, 12, 16–18 under 35 USC § 103(a) as being unpatentable over Lastovich in view of Clarke has been overcome and should be withdrawn.

Claims 2 and 15 are rejected under 35 USC § 103(a) as being unpatentable over Lastovich in view of Clarke in further view of U.S. Patent Publication 2002/0020688 (hereinafter Sherman).

Similar to its rejection of claim 1, the Patent Office rejects claim 2, asserting that Lastovich teaches at paragraph 48 "injecting the molten plastic material into the heated negative mold cavity [0048]". As discussed above with regard to claim 1, Applicants respectfully submit that the Patent Office has not established that Lastovich teaches, suggests or describes this aspect of claim 2.

The Patent Office does not point to anything in Clarke or Sherman to overcome this deficiency. Sherman does teach heating a mold to above the melting temperature of a plastic material that is coated onto the mold. This, again, has no bearing on the injection molding method claimed.

Accordingly, Applicants kindly submit that the rejection of claim 2 under 35 USC § 103(a) as being unpatentable over Lastovich in view of Clarke in further view of Sherman has been overcome and should be withdrawn.

Claim 15 adds additional features to claim 2. Claim 2 is patentable for the reasons given above. Thus, claim 15 is likewise patentable.

In summary, the rejection of claims 2 and 15 under 35 USC § 103(a) as being unpatentable over Lastovich in view of Clarke has been overcome and should be withdrawn.

Claims 4 is rejected under 35 USC § 103(a) as being unpatentable over Lastovich in view of Clarke in further view of U.S. Patent 6,076,248 (hereinafter Hoopman).

Claim 4 adds additional features to claim 3, which in turn depends from independent claim 1. Claim 1 is patentable for the reasons given above. The Patent Office does not point to anything in Hoopman that overcomes the deficiencies identified above with regard to the combination of Lastovich and Clarke. Thus, claim 4 is likewise patentable.

**Conclusion**

In view of the above, it is submitted that the application is in condition for allowance.  
Examination and reconsideration of the application as amended is requested.

Respectfully submitted,

September 24, 2009

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